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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,133	10/14/2004	Adrien Beaudoin	JG/13694.4	9225

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EXAMINER	
WOOD, AMANDA P	
ART UNIT	**PAPER NUMBER**
1657	

NOTIFICATION DATE	DELIVERY MODE
08/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,133	BEAUDOIN ET AL.	
	Examiner	Art Unit	
	Amanda P. Wood	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 31-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II (claims 12-30) in the reply filed on 11 June 2007 is acknowledged. The traversal is on the ground(s) that all the groups of inventions share at least one special technical feature that is not disclosed by Gendron et al (the reference cited by the Examiner to demonstrate a lack of unity amongst the inventions), namely the recital of NTPDase's direct activity in the immune response and the ability of NTPDase inhibitors to inhibit this activity. This is not found persuasive because the Examiner respectfully disagrees with Applicant's assertion that such a special technical feature is common to all the inventions. In particular, of Group I do not refer to the immune response or NTPDase's direct activity on immune response. Furthermore, Group I does not refer to inhibition of immune cell activity, only reduction of NTPDase activity in the presence of a candidate compound. In addition, Group II refers only to targeting immune cells with an NTPDase inhibitor. Furthermore, Kumamoto et al (US 7,067,254) teach a method wherein inhibitors of NTPDase are administered to individuals for hyperactive immune disorders, such as allergic response or autoimmune disorders. Therefore, the use of NTPDase inhibitors to target immune cells disorders cannot be considered a special technical feature. Therefore, based upon the lack of unity amongst the groups of inventions in addition to the lack of a special technical feature in the claims, Applicant's traversal of the restriction requirement is not deemed persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-30 are presented for consideration on the merits,

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 17-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particular cells, such as T lymphocytes, B lymphocytes, etc., it does not reasonably provide enablement for the entire genus of "immune cells," which encompasses any and all types of cells of the immune system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims Applicant provides examples of using NTPDase inhibitors on particular cell types found in the immune system, but does not provide adequate support to enable one of skill in the art to practice the invention on any and all cells that may be found in the immune system.

Claims 17 and 21-30 depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14, 16, 18-20, and 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, Applicant recites the phrase "inhibiting an immune cell activity" in line 1 of claim 12. It is unclear what Applicant means by the phrase "immune cell activity" (i.e., does Applicant intend to encompass allergic hypersensitivity reactions, such as release of histamines by sensitized mast cells, the process of phagocytosis by neutrophils, or does Applicant only intend to encompass lymphocyte proliferation and antibody production?).

Claims 13, 14, 16, 18-20, and 24-30 depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claims 12-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant recites the phrase "targeting immune cells" in line 2 of claim 12. It is unclear what Applicant means by "targeting immune cells" (i.e., what does Applicant intend to encompass by the word targeting? Does Applicant mean that only immune cells are affected by the NTPDase inhibitor, or are other cells also affected? Is some sort of vector used to specifically treat a subset of cells, or is the inhibitor just administered generally to the mammal?). In addition, targeting does not appear to be an active method step, but rather a mental step, and

therefore seems vague and indefinite. Furthermore, it is unclear whether Applicant intends to encompass all "immune cells" by the claim, or if the limitation is meant to only encompass certain cells of the immune system (i.e., would one want to inhibit the NTPDase activity of all cells in the immune system, or just a particular subset?).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites the limitation "inhibiting an immune cell activity in a mammal comprising targeting immune cells in the mammal with an effective amount of a NTPDase inhibitor, wherein said targeting inhibits the immune cell activity in the mammal" in lines 1-4. It is unclear how targeting immune cells with an NTPDase inhibitor relates to the preamble of "a method for inhibiting an immune cell activity in a mammal" in claim 12. There appears to be insufficient antecedent basis for this limitation in the claim. Furthermore, it appears that there may be elements missing in the claim which would link targeting immune cells with an NTPDase inhibitor with inhibiting immune cell activity (i.e., is there a particular means by which NTPDase inhibitors are targeted to immune cells, such as by administering them in some form to mammals, etc.? Does the NTPDase inhibitor have some particular effect on immune cells that is not the same as the effect on other types of cells?).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> Or
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-14, 16, and 22-23 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Kumamoto et al (US 7,067,254).

A method is claimed of inhibiting an immune cell activity in a mammal, comprising targeting immune cells in the mammal with an effective amount of an NTPDase inhibitor.

Kumamoto et al teach a method of inhibiting NTPDase-mediated immune activity in Langerhans cells (a type of dendritic cells, which are a type of immune cells), wherein the NTPDase activity corresponds to CD39. Kumamoto et al also teach that CD39 (NTPDase) activity is expressed in T cells, B cells, and natural killer cells (see, for

example, col. 14, lines 30-40). Kumamoto et al teaches that NTPDase inhibitors can be used to treat hyperactive immune disorders such as autoimmune disorders and allergies (i.e., NTPDases are used to target immune cells to inhibit the NTPDase activity of the cells). Kumamoto et al teach that changes in the levels of NTPDase in a cell can affect its immune response, such as increases in NTPDase levels can cause a hyrperactive immune response, such as allergies, and therefore, one suffering from such a response would benefit from inhibitors of NTPDase so as to reduce the NTPDase levels and activity of the cells. Kumamoto et al teach that decreases in activity can be affected by NTPDase inhibitors, antagonists, or suicide substrates (i.e., analogues) (see, for example, col. 33, lines 1-15).

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kukamoto et al in view of Beaudoin et al (US 6,617,439) and Komoszynski et.al (Comp. Biochem. Physiol. Part B 1996).

Kukamoto et al is relied upon for the reasons set forth above.

Beaudoin et al beneficially teach that ATP analogues such as 8-BuS-ATP are effective and inhibitors of NTPDases (see, for example, col. 4, lines 15-30). In addition, Beaudoin beneficially teach that in the immune system, modulation of NTPDase levels can include modulating the function of various immune cell types and the modulation of diverse responses of the immune system (see, for example, col. 6, lines 45-67).

Komoszynski et al beneficially teach that erythrosine B is useful for inhibiting mammalian NTPDases (see, for example, Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of inhibiting NTPDases in immune cells as disclosed by Kumamoto et al, based upon the beneficial teachings provided by Beaudoin et al, with respect to the art-recognized method of using ATP analogues to modulate various immune cell functions, and by Komoszynski et al, with respect to the art recognized use of erythrosine B as an inhibitor of NTPDase, as discussed above. Furthermore, Kumamoto et al particularly point out that varying levels of NTPDases can cause hyperactive immune disorders, such as allergies and autoimmune disorders, and that it would be beneficial to provide inhibitors of NTPDases to decrease their levels so as to treat or prevent the disorders, and therefore, it would have been obvious and beneficial for the skilled artisan to use the methods taught by Kumamoto et al, Beaudoin et al, and Komoszynski et al, so as to provide a method for inhibiting NTPDases in immune cells for such a purpose. Based upon Applicant's own admission, (see, for example, pg., 4 of the instant specification, reference to Gendron et al 2001) NTPDase inhibitors such as BGO 136 were known in the at the time the claimed invention was

made, and therefore, it would have been obvious to use such inhibitors and their analogues in the methods of Kukamoto et al, based upon the beneficial teachings provided by Beaudoin et al. One of skill in the art would recognize, based upon the teachings provided by Beaudoin et al, that by modulating the diverse responses of the cells of the immune system would encompass the responses of both normal and abnormal, or neoplastic, lymphocytes, including proliferation and production of antibodies. The result-effective adjustment of particular conventional working conditions (e.g., using a particular NTPDase inhibitor or targeting a particular type of immune cell) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

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GROUP 1200

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